

Message Text

UNCLASSIFIED

PAGE 01 STATE 094432

72

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 NEA-09 ISO-00 OES-05 MED-03

EB-07 COME-00 CIAE-00 DODE-00 INR-07 NSAE-00 PA-02

USIA-15 PRS-01 SP-02 /090 R

66608

DRAFTED BY: DEW/FDA: JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP: MBEAUBIEN

ARA/NSC-IG: RJBLOOMFIELD (INFO)

NEA/RA: TGRANT (INFO)

EA/RA: RMARTENS (INFO)

EUR/NSC-IG: JROUSE (INFO)

DHEW/OIH: MACODDING

----- 030726

R 241526Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY BRUSSELS

AMEMBASSY BRASILIA

AMEMBASSY HELSINKI

AMEMBASSY PARIS

AMEMBASSY JAKARTA

AMEMBASSY ROME

AMEMBASSY AMMAN

AMEMBASSY BEIRUT

AMEMBASSY MEXICO

AMEMBASSY WELLINGTON

AMEMBASSY PANAMA

AMEMBASSY LIMA

AMEMBASSY LISBON

AMEMBASSY SINGAPORE

AMEMBASSY MADRID

AMEMBASSY STOCKHOLM

AMEMBASSY CARACAS

AMEMBASSY LONDON

UNCLAS STATE 094432

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 094432

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: INADEQUATELY LABELED DIAGNOSTIC MEDICAL DEVICE

FDA ADVISES THAT THE MODEL E-10-C TREADMILL, MANUFACTURED BY AVIONICS BIOMEDICAL DIVISION, DEL MAR ENGINEERING LABORATORIES, 4901 WEST IMPERIAL HIGHWAY, LOS ANGELES, CALIFORNIA, SERIAL NOS. 1 THROUGH 855, MAY BE DEFECTIVE FOR THE FOLLOWING REASON: THERE IS THE POSSIBILITY OF ERRATIC HIGH SPEED RUNNING OF THE CONVEYOR BELT WHEN TURNED ON FROM THE RESET POSITION AFTER THE UNIT HAS SHUT DOWN DUE TO AN OVERSPEED SITUATION. THE OVERSPEED SHUT DOWN MAY RESULT FROM FAILURE OF SILICON CONTROLLED RECTIFIERS SCR-2 OR SCR-3, AND CAUSE ERRATIC OR UNCONTROLLED BELT SPEED WHEN THE SPEED CONTROL KNOB IS TURNED TO THE RESET POSITION.

THE FIRM SENT A SERVICE INFORMATION REPORT, NO. 1070, DATED FEB 22, 1974, TO ALL CONSIGNEES OF THIS PRODUCT, CONSISTING OF A WARNING STATEMENT THAT IS TO BE ADDED TO THE OPERATIONS MANUAL FOR THE DEVICE AND AN ADHESIVE WARNING STICKER TO BE PLACED UPON THE DEVICE.

POSTS ARE REQUESTED TO ASCERTAIN WHETHER CONSIGNEES HAVE RECEIVED SERVICE INFORMATION REPORT BULLETIN NO. 1070 AND THE ADHESIVE WARNING STICKER TO BE PLACED ON THE DEVICE.

FOREIGN CONSIGNEES AS FOLLOWS:

MEDICAL ELECTRONICS & EQUIPMENT PTY, LTD.
51-53 CONCORD ROAD
CONCORD, N.S.W. 2137, AUSTRALIA

PAUL LOUIS
DIVISION OF AHS, BELGIUM
CHAUSSÉE DE ZELLIK, NO. 30
B-1080
BRUSSELS, BELGIUM

SEARLE NUCLEAR DO BRASIL
RUA TEODORO SAMPAIO, 417
CONJ. 63/64
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 094432

05405 SAO PAULO, BRASIL

INSTRUMENTARIUM
ELIMAENKATU 22
00510 HELSINKI 51, FINLAND

KONTRON S.A.
15 RUE DU DOME

92100 BOULOGNE, FRANCE

GENERAL INDUSTRIAL ENGINEERING
P.T. UNITED DICO CITAS CO. LTD.
P.O. BOX 537/JAK
JOLAN PENJORINGAN 39A
JAKARTA BARAT, INDONESIA

CARLO ERBA STRUMENTAZIONE
DIV. RES MEDICIS
STRADA RIVOLTANA
20090 RODANO (MILANO)
ITALY

MUNIR SUKHTIAN CO. LTD.
P.O. BOX 1027
AMMON, JORDAN

CONSTANTIN E. MACRIDIS
P.O. BOX 7213
CLEMENCEAU CENTER
CLEMENCEAU STREET
BEIRUT, LEBANON

SEARLE DE MEXICO, S.A
APARTADO 1848
MEXICO 1, D.F. MEXICO

FLETCHER STEEL
HEALTH AND SCIENCE DIVISION
PRIVATE BAG
AUCKLAND, NEW ZEALAND

UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 094432

EXECUTIVE MARKETING CORPORATION
APARTADO 4929
PANAMA 5, R. DEP.
PANAMA

COMPANIA ELECTRO MEDICA, S.A.
CASILLA 1030
LIMA, PERU

MUNDINTER
AV. ANT. AUG. AQUIAR 138
APARTADO 2761
LISBON, PORTUGAL

E.I. PARRISH (SINGAPORE) PTE. LTD.

JOLON TUKANG, JURONG
P.O. BOX 57 TAMAN JURONG
SINGAPORE 22, SINGAPORE

ATARO INGENIEROS, S.A.
ENRIQUE LARRETA 12
MADRID 16, SPAIN

LANDSTINGENS INKOPSCENTRAL
5-171 83 COLNA
SWEDEN

DISTRIBUIDORA NACIONAL, C.A.
APARTADO 70383 - LOS RUICES
CARACAS 107, VENEZUELA

F.F. PALMER (LONDON) LTD.
LANE END ROAD
HIGH WYCOMBE, BUCKS, ENGLAND

KISSINGER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: n/a
Control Number: n/a
Copy: SINGLE
Draft Date: 24 APR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE094432
Document Source: CORE
Document Unique ID: 00
Drafter: DEW/FDA: JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: n/a
From: SECSTATE WASHDC
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750417/aaaaaqae.tel
Line Count: 190
Locator: TEXT ON-LINE
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: ShawDG
Review Comment: n/a
Review Content Flags:
Review Date: 08 JUL 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <08 JUL 2003 by SilvaL0>; APPROVED <03 FEB 2004 by ShawDG>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: INADEQUATELY LABELED DIAGNOSTIC MEDICAL DEVICE
TAGS: OGEN, ETRD, TBIO, XX
To: CANBERRA BRUSSELS BRASILIA HELSINKI PARIS JAKARTA ROME AMMAN BEIRUT MEXICO
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006